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The QUOVADIS Study: Features of obese Italian patients seeking treatment at specialist centers

N. Melchionda*, G. Marchesini*, G. Apolone**, M. Cuzzolaro***, E. Mannucci****
and E. Grossi***** for the QUOVADIS Study Group[1]

ABSTRACT. **Obesity is a major risk factor for several chronic diseases, but the burden associated with it also extends to psychosocial areas and to perceived health status. In 1999 an observational study on health-related quality of life in obesity was planned. The study was entirely web-based. Case Report Forms and the individual items of 7 self-administered questionnaires were directly implemented on a general database via an extranet system from 25 Italian centers. By December 2001, after enrolment had stopped, the database included anthropometric, socioeconomic and clinical data of 1944 patients (78% females). Weight-cycling was reported in over 80% of cases, overeating in 60-65%, structured physical activity in only 13-15%. Several chronic illnesses were associated. Whereas the prevalence of diabetes and hypertension was related to the degree of obesity, hyperlipidemia and coronary heart disease did not increase further with increasing obesity. A disturbed psychological mood was twice more common in females. Concern for present health was the main reason for seeking treatment in both genders; concern for body appearance was more common in females. Male subjects were more frequently assigned to dietary counseling and physical exercise, whereas in females psychotherapy was more frequently considered. Various forms of behavioral approach were planned in approximately 50% of patients. Finally, very few patients were initially considered for pharmacological intervention or bariatric surgery. The study provides a comprehensive picture of Italian patients seeking treatment for obesity. Data on perceived health status, psychological well being, body image awareness, eating behavior disorders and psychopathological distress will provide clues to a comprehensive assessment of obesity, the effects of treatments and reasons for failure.**
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INTRODUCTION

There is an increasing concern for the burden associated with obesity. Although some areas of the medical community, including care providers, still consider obesity a cosmetic problem, the prevalence of the disease has reached the proportion of a worldwide epidemic (1). Obesity is a major risk factor for several diseases, namely diabetes, hypertension and hyperlipidemia, all contributing to cardiovascular diseases (2, 3), reducing life expectancy (4), and expensive to manage (5). Dynamic models indicate that life expectancy is reduced in relation to body mass index (BMI) (6), while weight loss improves life expectancy and leads to lifetime health and economic benefits (7).

The morbidity from obesity-associated disorders is not limited to somatic diseases. Most patients experience a series of psychological disturbances, enhanced by the social stigma of obesity, and by the discrimi-

[1]The QUOVADIS Study Group.
Coordinator: N. Melchionda (Università di Bologna). *Steering Committee:* N. Melchionda, G. Marchesini (Bologna), G. Apolone (Milano), M. Cuzzolaro (Roma), E. Mannucci (Firenze), E. Grossi (Milano). *Participants:* S. Avagnina°, L. Ferrero (Torino 1-100 cases), E.G. Barantani°, E. Molinari°, M.L. Petroni°, R.M. Marsala, A. Compare, S. Hacker (Piancavallo-157), F. Belfiore° (Catania-6), F. Caviezel°, B. Ambrosi°, A. Tufano (Milano 1-56), F. Corica°, A. Corsonello, D. De Domenico (Messina-80), M. Cuzzolaro°, V. Giancotti, M. Valentini, S. Antonini (Roma 1-146), E. Dall'Aglio°, A. Adami (Parma-64), R. Dalle Grave°, C. Scutari (Garda-41), G. Del Rio°, M. Bondi, R. Menozzi (Modena 1-100), G. Fatati°, M. Palazzi (Terni-53), M.A. Fusco°, M.G. Carbonelli (Roma 2-54), M. Gennaro°, L. Scaglione, K. Rossin (Sanremo-73), L. Lucchin°, R. Trovato (Bolzano-30), G. Marchesini°, S. Natale, L. Baraldi, G. Forlani, N. Villanova (Bologna-202), A.M. Ciccarone°, K. Chatzianagnostou (Pisa-89), R.F. Novi°, A. Trombetta, M.A. Seardo, G.F. Alberto (Torino 2-105), E.A. Pontiroli°, A. Saibene, P. Vedani (Milano 2-69), C. Rotella°, S. Ciani, T. Zucchi (Firenze-91), G. Salvioli°, P. Ventura, L. Morselli (Modena 2-70), F. Tomasi°, S. Barbieri, E. Scalambra (Ferrara-150), F. Capani°, E. Vitacolonna, M. Taraborrelli (Chieti-50), C. Noacco°, C. Taboga, S. Mreule (Udine-60), E. Ferrari°, F. Magri (Pavia-60), P. Beck Peccoz°, P.S. Morpurgo (Milano 3-53), M. De Rosa, A. Covezzoli, F. Campana (CINECA, Bologna), E. Grossi, G. Rivolta, D. Cerutti (BRACCO Imaging spa, Milano). °Principal Investigator. The number of cases enroled in each center is in parentheses.

*University of Bologna, **"Mario Negri" Institute of Pharmachological Research, Milan, ***"La Sapienza" University, Rome, ****University of Florence, Florence, and *****Bracco Imaging S.p.A., Milan, Italy.

Key words: Obesity, anthropometry, quality of life, behavior, therapy.

Correspondence to: Prof. Giulio Marchesini, Servizio di Malattie del Metabolismo, Università di Bologna, Azienda Ospedale S. Orsola-Malpighi, Via Massarenti 9, I-40138 Bologna, Italy.
E-mail: marchreg@med.unibo.it

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nation patients suffer in several areas of everyday life (8-10). Anxiety and depression are often present (11-13), although conflicting data have been reported on their exact prevalence in the obese population (14, 15). A few patients have a binge eating disorder (BED) (16), which is now classified as a definite psychiatric disturbance in the 4th edition (Text Revision) of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV-TR) (17), in the subcategory of "eating disorders non-otherwise specified". Finally, the treatment of obesity and food restriction may exacerbate or produce psychological distress, which largely outweighs the beneficial effects of weight reduction.

All these factors are expected to impair the health-related quality of life (HRQL) of obese persons. The measurement of HRQL through specific questionnaires has gained widespread consideration and is now accepted as a major outcome of treatment in chronic conditions (18), where life is not at risk for several years. Obesity is a good example of such diseases, and several studies have documented a poor HRQL in obese subjects, both seeking and not seeking treatment at specialist centers for their excessive body weight (19-27). Previous studies have usually addressed a specific area of HRQL and psychological distress and a complete assessment of mood and behavior has never been reported. In addition, sociocultural differences are probably relevant, and only few data have been reported in the Italian population (28).

A large database was recently established in Italy for a comprehensive measurement of HRQL, psychological distress and eating behavior in obese patients. The QUality of life in Obesity: eVAluation and DIsease Surveillance (QUOVADIS) study is an observational study aimed at providing a complete picture of obese patients seeking treatment at obesity Italian centers. The present report identifies the population under study in terms of sociocultural, anthropometric and clinical characteristics, together with life-style and daily habits. The methodology used to implement data into the database and the different questionnaires used to measure HRQL and psychological distress are also reported.

MATERIALS AND METHODS

QUOVADIS study planning

In 1998 a steering committee was created to organize an observational study on HRQL in obese patients seeking treatment at specialist centers, with the funding support of Bracco Imaging Spa, Milano. After 2 meetings where a general draft was planned, the steering committee invited several Research Units working on obesity in different geographical areas of Italy to participate in the study. A general investigator meeting was organized to decide selection criteria, to agree on a data collection form, to standardize the handling of questionnaires and management of patients. Twenty-two Italian centers with specific interest on clinical research in obesity were involved. They were expected to enrol approximately 1800-2000 new patients in a 12-month period. Each center was appointed for a maximum number of patients, and stopped recruitment after completing the allotted number.

To expedite handling of data, CINECA (Casalecchio di Reno, Bologna, Italy), an Interuniversity Consortium of 15 Italian Universities, provided an extranet system using Advanced Multicenter Research (AMR) methodology. AMR is a web-based application, previously developed by CINECA as a result of an extensive co-operation of clinicians, statisticians and informatics, which allows the management of the whole research using standard web-browsers. Participating centers access the system using a personal user-ID and password and insert patients' data into the database through electronic forms. High quality level of data is guaranteed by up-front quality controls (on client side) and consistency checks (on server side). Investigators cannot modify the information sent to the central database. Each center has access to its own data whereas the co-ordinating center (Servizio di Malattie del Metabolismo, University of Bologna) was allowed to look over the whole database, and to correct errors after notification from peripheral centers. In the event of changes, the system registers all the information (old and new value, modification time and reason for change). The system is very flexible and offers the possibility of obtaining real-time reports on demand. A different tool (direct analysis) allows online descriptive statistics and data analysis.

The database was implemented using Oracle, Release 7.3.4.4.0 (Oracle Corporation, Redwood Shores, CA), a relational database management system. Security is granted by the IANUS system developed by CINECA, which provides a secure system management technology in Internet applications, and Secure Socket Layer (SSL) to encrypt all transactions.

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In the course of the study one center failed to enrol patients, whereas 4 more centers entered the group during the year 2000. The 25 centers were scattered throughout Italy, from the north (Turin, Bozen, Udine) to the south (Catania, Messina).

Protocol

All obese subjects seeking treatment were eligible for the study, provided they were not on active treatment at the time of enrolment, were in the age range between 25 and 65, agreed to fill the whole package of self-administered questionnaires, and signed an informed consent to participate.

The protocol included a Registration Form, to be filled in at the time of the first visit, a Case Report Form, a Therapeutic Program Form, a package of questionnaires for HRQL, psychological distress and eating behavior disorders, and a follow-up form, to be filled in at 6- and 12-month follow-up.

The Registration Form was extremely simple, since all patients could be enroled, provided their BMI was in the obesity range (≥30 kg/m^2), they were not on active treatment for obesity at the time of enrolment, and gave informed, signed consent to participate.

The Case Report Form included information on civil and educational status, on family history of metabolic and cardiovascular diseases, on awareness of personal metabolic and cardiovascular diseases, and any information on specific conditions usually associated with obesity (sleep disorders, articular diseases, psychological distress). It also included detailed information on number and results of previous attempts to lose weight, on expected weight loss in the following 6 and 12 months, on maximum acceptable weight and on desired weight.

HRQL and psychological well being were tested by self-administered questionnaires. To have a broad spectrum of perceived health status and psychopathological status, the steering committee proposed the use of 7 questionnaires [Medical Outcome Survey Short-Form 36 (SF-36), Obesity-Related Well Being (ORWELL-98), Psychological General Well Being Index (PGWBI), Three-Factor Eating Questionnaire (TFEQ), Binge Eating Scale (BES), Body Uneasiness Test (BUT), Symptom CheckList-90 (SCL-90)].

The SF-36 (29) is a specifically constructed questionnaire to measure the full range of health status and well being by means of 36 multiple-choice questions. It measures 8 different domains, 4 in the area of mental health (Role Limitation-Emotional, Vitality, Mental Health, and Social Functioning), and 4 in the area of physical health (Physical Functioning, Role Limitation-Physical, Bodily Pain, General Health). Two comprehensive indexes of HRQL (Mental Component Summary, Physical Component Summary) may also be computed. Finally, it provides an estimation of the self-perception of the change in health status during the last year. It has been extensively validated worldwide and in its Italian version (30).

The ORWELL-97 (31) is an obesity-specific questionnaire (18 items) that was recently validated to measure the intensity and the subjective relevance of physical and psychological distress generated by overweight. It is particularly useful to measure changes in perceived health status following changes in body weight.

The PGWBI (32) is a measure of mood and emotional status reflecting subjective well being. The responses to 22 questions are arranged in 6 affective states: anxiety, depressed mood, positive well-being self-control, general health and vitality. The Italian version of the questionnaire has been recently validated.

The TFEQ (33) includes 36 items with an agree/disagree format and 15 items on 4 response scales. All item responses are aggregated into 3 main factors: restrained eating, disinhibition and hunger. Restrained eating measures the amount of intentional restraining on food intake; disinhibition measures the loss of control on eating pattern and social/emotional eating; hunger measures subjective feeling of hunger.

The BES (34) includes 16 items measuring the severity of the binge eating disorder. It examines both behavioral manifestations (eating large amounts of food) and feeling/cognition during a binge episode (loss of control, guilt, fear of being unable to stop eating).

Both TFEQ and BES have been translated into Italian and validated by the NetWorking Team Group of the Italian Society for Eating Behavior Disorders (SIS-DCA).

The BUT is a new self-administered, rapid questionnaire specifically developed to evaluate concern for physical appearance, body image awareness (34 items) and body parts which more severely contribute to body dissatisfaction (37 items).

The SCL-90 (35) is an easy tool to identify psychopathological distress. For each item, patients

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score how much that problem has distressed them during the last week, with responses ranging from 0 (not at all) to 4 (extremely). The 90 items of the test are summarized into 9 domains (somatization, obsessive-compulsive thoughts, interpersonal sensitivity, depression, anxiety, hostility, phobic anxiety, paranoid conceiving, psychotic behavior), and a general symptom index (GSI), which is used as an indicator of the overall psychological distress.

The total number of items of the 7 questionnaires is 304. A specific protocol was devised to submit questionnaires to patients at different times in the course of the enrolment visit, to maintain their attention to questions. The questionnaires are rigidly self-administered, but personnel in each center were trained to check completeness of data. Whenever data were missing at first check, patients were asked to complete the questionnaires, and instructions were given when needed, without forcing answers.

The Therapeutic Program Form included data on planned therapeutic program for any individual patient. The study was expected to be observational. Accordingly, centers were expected to treat patients along the lines of their specific programs, including dieting, cognitive behavioral therapy, drugs and bariatric surgery.

The Follow-up Format was designed to register any modification of body weight, clinical and laboratory variables after 6 and 12 months of therapy, together with the actual treatment received by patients, irrespective of the tentative treatment outlined in the Therapeutic Program Form. It was also used to register dropouts and any problem encountered by patients during the follow-up.

The protocol was approved by the Ethics Committees of the individual centers, after approval of the ethical committee by the coordinating center (Azienda Ospedaliera di Bologna, Policlinico S. Orsola - Malpighi).

Statistical analysis

Differences between gender groups were analyzed by means of unpaired *t* test or rank sum test, whenever appropriate. X^2 analysis (2 x 2 or R x C) was used for contingency tables. Statistical significance was set at *p*-values <0.05.

RESULTS

The study officially started in February 2000 and stopped on November 31, 2001. The recruitment curve is presented in Figure 1. As expected, the number of patients increased steadily in the course of the year 2000, reaching a plateau by the first trimester of 2001. At this time, the final increase in the number of enroled patients was almost completely due to centers where the recruitment had started later.

Female patients accounted for nearly 78% of the enroled population (Table 1), with large variations among different centers (from 59.6 to 97.1) (p=0.0002, X^2 test). There were no differences between genders in the age distribution; also the BMI and the distribution according to the severity of obesity were similar. Only 5-6% of the population did not reach the threshold of waist circumference for the diagnosis of visceral obesity, whereas the waist-to-hip ratio was below the cut-off for visceral obesity in approximately 50% of males and two thirds of females.

Male patients had a higher educational level, a different civil status and a different job distribution.

The large majority of both males and females had previously been involved in weight-reducing programs, and in a few of them the number of previous attempts was exceedingly large (Table 2). The prevalence of patients spending most of their time sitting was higher in males, as was the prevalence of subjects involved in tiring jobs. Only 13-15% of patients were involved in a structured physical activity, but very few spent at least 1 hr/day exercising.

When patients were asked to score their life-style, males were more likely to score it either as extreme-

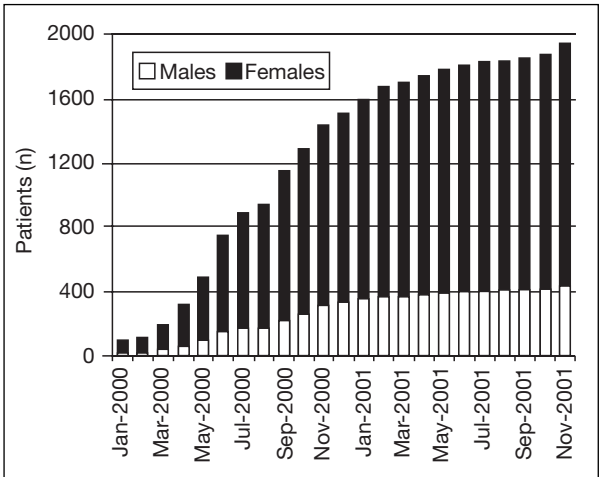

Fig. 1 - *Registration curve in the course of the study. Males are identified by open columns, black columns are females.*

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Table 1 - *Characteristics of patients under study (mean±SD or prevalence and 95% CI).*

	Males	Females	*p**
Gender	432	1512	
Age (yr) (median and range)	44 (24-64)	46 (18-65)	0.098
≥45 yr	48.9 (44.0-53.7)	54.0 (51.4-56.5)	0.769
Body mass index (kg/m^2) (median and range)	36.5 (30.0-82.2)	36.8 (30.0-70.0)	0.453
Obesity class			0.385
Class I (30-34.9 kg/m^2)	41.2 (36.6-45.9)	37.7 (35.2-401)	
Class II (35-39.9 kg/m^2)	27.6 (23.4-31.9)	28.4 (26.1-30.7)	
Class III (≥40 kg/m^2)	31.2 (26.8-35.7)	33.9 (31.5-36.4)	
Waist circumference (cm)	121±15	107±14	<0.0001
>102 cm (males) or >88 cm (females)	93.9 (90.9-95.7)	94.8 (93.5-95.8)	0.475
Waist-to-hip ratio	1.00±0.07	0.87±0.08	<0.0001
>1.0 (males) or >0.9 (females)	44.7 (39.8-49.4)	30.6 (28.1-33.1)	<0.0001
Education			<0.0001
Primary	10.4 (7.7-13.5)	19.8 (17.8-21.9)	
Secondary	29.9 (25.6-34.3)	35.8 (33.4-38.3)	
Commercial or vocational	48.9 (44.0-53.6)	37.4 (34.9-39.9)	
Degree	10.8 (8.1-14.1)	7.0 (5.7-8.4)	
Civil status			<0.0001
Single/divorced	27.5 (23.3-31.8)	20.6 (18.6-22.7)	
Married/co-habitating	71.3 (66.7-75.3)	74.0 (71.6-76.2)	
Widowed	1.2 (0.4-2.6)	5.4 (4.3-6.4)	
Employment status			<0.0001
Student	2.2 (1.1-3.9)	1.9 (1.3-2.7)	
Self-employed	27.5 (23.3-31.8)	7.6 (6.3-9.1)	
Employee	38.6 (33.9-43.2)	33.2 (30.8-35.6)	
Housewife	-	26.1 (23.9-28.4)	
Unemployed	2.9 (1.6-4.8)	3.7 (2.8-4.8)	
Retired	13.2 (10.2-16.7)	13.1 (11.4-14.9)	
Other	15.7 (12.4-19.3)	14.3 (12.6-16.2)	

*Unpaired *t* test, Wilcoxon rank sum test, or X^2 test.

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ly sedentary or as extremely active. No differences were present for eating patterns. Two-thirds of males and over 60% of females admitted to eating a larger-than-normal amount of food. The prevalence of active or previous alcohol drinkers and cigarette smokers was higher in males.

Several patients were aware of chronic illnesses (Table 3), causing hospital admission during the last year in 15-22% of cases. Diabetes, hypertension, hyperlipidemia and coronary heart disease (angina, myocardial infarction, coronary by-pass) were more frequent in males. The prevalence of clinically significant peripheral arterial disease was very low. Whereas diabetes and hypertension were significantly related to the degree of obesity, for hyperlipidemia and coronary heart disease no increase was observed in relation to increasing severity of obesity (Fig. 2).

Gallstone disease or previous cholecystectomy were approximately three times more common in females, whereas snoring was much more common in males, with increasing prevalence in relation to obesity class [Class I, 47.2% (95% CI, 43.5-50.9); Class II, 56.0 (95% CI, 51.6-60.1); Class III, 67.2 (95% CI 63.3-70.7); $p<0.0001$].

The prevalence of reported pain in the hip and knee joints was more common in females, and strictly associated to the degree of obesity ($p=0.011$ and $p<0.0001$, respectively), reaching a prevalence of 35.2% for hip pain (95% CI, 31.4-38.9) and 51.7% for knee pain (95% CI, 47.7-55.6) in Class III patients. A previous diagnosis of a disturbed psychological

mood was twice more common in the female gender, whereas thyroid diseases were four times more common. Finally, hormone-related tumors and colon cancer had previously been diagnosed in a limited number of patients.

When forced to select a sole item as the main reason for seeking treatment for their obesity, concern for present health was the principal reason for both males and females. Concern for body appearance was more likely to be a problem in females, and mainly in female patients with Class I obesity (20.6%; 95% CI, 17.3-24.0).

In the large majority of patients, planned treatment was still based on dietary prescription (Table 3). Male subjects were more frequently addressed towards dietary counseling and physical exercise, whereas in female subjects, a definite psychotherapy was more frequently considered. Various forms of behavioral approach (self-help, guided self-help, psychoeducation, or a formal cognitive-behavioral treatment) were used in approximately 50% of patients. Finally, very few patients were considered for pharmacological intervention or bariatric surgery at first assessment.

DISCUSSION

The present report identifies the main characteristics of obese Italian patients seeking treatment in specialist centers. These centers were partly university-based, partly non-academic, and scattered throughout Italy, to give a comprehensive picture of the main features

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Table 2 - *Self-evaluation of diet history and life-style in patients under study (mean±SD or prevalence and 95% CI).*

	Males	Females	*p**
Previous attempts to lose weight	72.3 (67.7-76.3)	85.4 (83.4-87.1)	<0.0001
N of attempts (median)	3 (1-over 20)	4 (1-over 20)	0.0019
Daily life and job style			<0.0001
Sitting	56.4 (51.5-61.0)	43.3 (40.7-45.8)	
Standing	24.1 (20.1-28.3)	36.3 (33.9-38.8)	
Walking	13.0 (10.0-16.5)	17.2 (15.3-19.2)	
Carrying loads	4.3 (2.7-6.6)	1.5 (0.9-3.6)	
Other	1.9 (0.9-3.6)	1.7 (1.1-2.4)	
Structured physical activity	13.0 (10.0-16.5)	14.9 (13.1-16.8)	0.341
Hours/week (median and range)	3 (1-15)	2 (1-28)	0.0017
Self-evaluation of life-style			0.0003
Very sedentary	21.0 (17.2-25.0)	17.5 (15.6-19.6)	
Moderately sedentary	37.6 (32.9-42.2)	36.0 (33.5-38.5)	
Normal	23.4 (19.4-27.6)	27.5 (25.2-29.8)	
Moderately active	14.7 (11.5-18.3)	18.2 (16.2-20.2)	
Very active	3.4 (1.9-5.4)	0.8 (0.4-1.3)	
Self-evaluation of eating pattern			0.092
Eat much less than normal	0.5 (0.1-1.5)	0.4 (0.2-0.9)	
Eat less than normal	2.9 (1.6-4.8)	5.0 (4.0-6.3)	
Eat a normal amount of food	28.7 (24.4-33.1)	32.4 (29.9-34.8)	
Eat more than normal	45.1 (40.2-49.8)	43.9 (41.3-46.4)	
Eat much more than normal	22.9 (19.0-27.0)	18.1 (16.2-20.1)	
Alcohol drinkers			<0.0001
Active drinkers	35.2 (30.6-39.8)	15.5 (13.7-17.4)	
Previous drinkers	3.9 (2.3-6.0)	1.5 (0.9-2.2)	
Cigarette smokers			<0.0001
Active smokers	27.5 (23.3-31.8)	21.1 (19.0-23.3)	
Previous smokers	33.3 (28.8-37.8)	19.6 (17.6-21.7)	

*Mann-Whitney or X^2 test.

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Table 3 - *Awareness of physical problems, reasons for entering a weight-reducing program, and planned treatment (prevalence and 95% CI).*

	Males	Females	p*
Hospital admission in the last year	18.6 (15.0-22.4)	17.5 (15.6-19.5)	0.616
Diabetes	12.8 (9.8-16.2)	8.3 (7.0-9.8)	0.008
Hypertension	43.9 (39.0-48.5)	34.6 (32.1-37.1)	0.0007
Hyperlipidemia	31.6 (27.2-36.1)	20.0 (18.0-22.1)	<0.0001
Coronary heart disease	5.8 (3.8-8.3)	1.7 (1.2-2.5)	<0.0001
Myocardial infarction	3.1 (1.8-5.1)	0.9 (0.5-1.5)	0.0007
Coronary by-pass	0.7 (0.2-1.9)	0.2 (0.1-0.6)	0.139
Peripheral vascular disease	0.2 (0.0-1.1)	0.1 (0.0-0.4)	0.665
Aorto-iliac by-pass	0.2 (0.0-1.1)	0.1 (0.0-0.3)	0.394
Carotid thrombo-endoarterectomy	0.0 (0.0-0.7)	0.1 (0.0-0.3)	0.591
Gallstones	6.0 (4.0-8.6)	15.9 (14.0-17.8)	<0.0001
Cholecystectomy	3.4 (1.9-5.4)	10.2 (8.7-11.8)	<0.0001
Snoring	71.3 (66.7-75.4)	52.0 (49.4-54.5)	<0.0001
Hip pain	20.5 (16.8-24.5)	34.0 (31.6-36.5)	<0.0001
Knee pain	29.9 (25.6-34.3)	44.1 (41.5-46.6)	<0.0001
Psychopathological distress	9.9 (7.3-13.0)	20.6 (18.6-22.8)	<0.0001
Previous cancer	3.4 (1.9-5.4)	8.3 (7.0-9.8)	0.0002
Uterus		4.1 (3.2-5.2)	-
Breast	0.2 (0.0-1.1)	2.4 (1.7-3.3)	0.0006
Colon	0.5 (0.1-1.5)	0.6 (0.3-1.1)	0.846
Others	2.7 (1.4-4.5)	2.0 (1.4-2.9)	0.612
Thyroid diseases	4.1 (2.5-6.3)	18.2 (16.3-20.3)	<0.0001
Menstrual disorders	-	17.9 (16.0-19.9)	-
Hirsutism	-	8.0 (6.7-9.5)	-
Main reason for seeking treatment			<0.0001
Concern for appearance	7.2 (5.0-10.0)	17.3 (15.4-19.3)	
Concern for present health	56.1 (51.2-60.7)	50.0 (47.4-52.6)	
Concern for future health	36.6 (32.0-41.2)	24.7 (22.8-26.7)	
Planned treatment**			
Dietary prescription	76.4 (71.4-80.6)	76.3 (73.7-78.6)	0.952
Dietary counseling	51.7 (46.1-56.8)	45.5 (42.5-48.3)	0.046
Physical exercise	59.5 (53.9-64.5)	52.5 (49.3-55.1)	0.021
Behavioral approach	46.4 (40.9-51.6)	53.4 (50.4-56.2)	0.190
Psychotherapy	1.5 (0.6-3.3)	3.8 (2.8-5.0)	0.027
Drug therapy	7.8 (5.3-11.1)	7.7 (6.3-9.3)	0.937
Bariatric surgery	1.8 (0.7-3.7)	2.1 (1.4-3.1)	0.735

*X^2 test. **Treatments are not mutually exclusive.

of obese Italians and of treatment strategies, because of its observational planning. Selection criteria were extremely wide, and only age range prevented the inclusion of the few patients who were either too young (<25 yr) or elderly (>65 yr). According to data recently published by one Italian center (28), which enroled over 10% of the total present population, subjects younger than 25 yr account for less than 10% of non-pediatric patients seeking weight-reducing treatment for obesity, whereas subjects older than 65 are rarely selected for intensive programs.

The study was specifically aimed at giving a picture of HRQL, psychological distress, eating behavior and body image disorders, both at entry and after a follow-up of 6 and 12 months. These data will be presented in a specific report.

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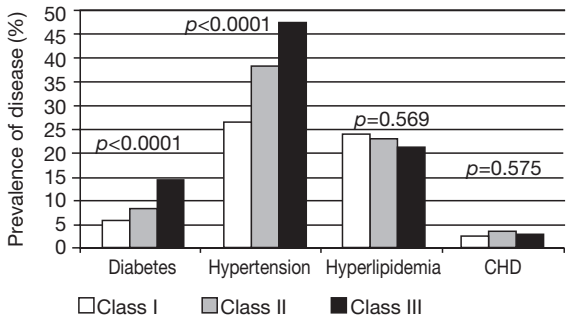

Fig. 2 - *Prevalence of diseases in relation to obesity class. Class I patients have a body mass index (BMI) in the range 30-34.9 kg/m^2, Class II patients have a BMI in the range 35-39.9 kg/m^2, Class III patients have a BMI≥40 kg/m^2. P-values (X^2 test) identify differences between classes. CHD=coronary heart disease.*

In relation to data presented here, several points need to be discussed. Firstly, females accounted for nearly 80% of cases. Gender distribution significantly varied among centers, but in all centers the number of females exceeded the number of males. This fits with all studies of obesity where patients are recruited on the basis of self-referral for treatment (2, 25, 28), but contrasts with epidemiological studies showing that obesity affects males and females in nearly identical rates, with only a modest prevalence of female gender (1, 19, 26, 36). This evidence is a matter of concern for specialists involved in the treatment of obesity. Obesity increases cardiovascular risk, and males, because of their visceral adiposity and lack of hormonal protection, are at greater risk than females. Unfortunately, the motivation for entering a weight-reducing program is much higher and different in females; males are frequently in a pre-contemplative or contemplative state (37), are not seriously considering the possibility of permanent life-style changes to cope with their excessive weight, or claim they have no time to care for their person.

Motivation is an important issue. In the present population, nearly 20% of females considered their body appearance the principal reason for entering a weight-reducing program. This figure probably underestimates the importance of concern for body appearance in the general population of obese females because of a referral bias to medical centers. In males, concern for body appearance was exceedingly rare, but were this reason equally important for males and females, still the number of males seeking treatment would remain much lower than that of females. Educational programs are needed to move male obese patients towards treatment, and to help them to remove obstacles and the distress about what they have to give up to achieve change (38).

Secondly, several aspects of daily life of obese patients need comments. According to the referred number of previous attempts to lose weight, weight-cycling is the rule, both in males and in females, pointing to a low compliance to weight-reducing programs in both sexes. Also in this case a referral bias to medical centers may increase the number of weight-cyclers in comparison to the general obese population. However, this evidence opens the question what is standard treatment for obesity. Do we need to follow patients as long as they lose weight to a pre-definite target, or follow-up must be indefinitely maintained to minimize dropouts and weight regain? Apparently, present strategies do not guarantee long-term results.

The distribution of obesity is fairly representative of the general trend of obesity in Italy. However, different centers enroled patients according to their specific protocols, and the prevalence of obesity classes was extremely variable. One center enroled 96% of patients with Class III obesity, whereas another had no patients with Class III and 79% with Class I obesity. Far from being a bias of the study, this will allow a more comprehensive assessment of the various strategies of treating obesity of different severity in different settings.

As expected, planned treatments were extremely variable. The low number of patients scheduled for bariatric surgery probably represents a recruitment bias. All participating centers were medical centers and, although a few of them were actively involved in protocols of bariatric surgery, this option is probably underestimated in our series with Class III obesity in comparison to the general Italian patients with morbid obesity.

Data on life-style will allow a reasonable frame to evaluate effectiveness of these various weight-reducing strategies and HRQL. A special focus was dedicated to physical activity, because of its primary importance on fat deposition and weight maintenance after weight loss (4, 39). Although self-report of physical activity is not very accurate (40), this is the necessary prerequisite to activate behavioral changes (38). This consideration also applies to self-evaluation of eating pattern.

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Finally, awareness of somatic diseases is of paramount importance to ascribe impaired HRQL to obesity and not to any complicating disease. Whereas the presence of diabetes, hypertension and hyperlipidemia was of the same magnitude as expected, the presence of vascular diseases, either coronary or peripheral, was exceedingly low in the present population. These data suggest that patients with severe disease do not seek treatment for losing weight at obesity centers, but are probably treated in cardiology units, with unknown results. It is time to integrate competence towards a proper management of obese patients (41).
The last consideration is for therapeutic intervention. A formal dietary prescription is still considered in the majority of patients, despite its very poor effectiveness (42), and largely exceeds the treatment option of dietary counseling and behavioral approach. A life-style behavioral program, in its various forms, was considered in approximately 50% of cases, confirming that this approach remains a cornerstone of therapy (43) and may be introduced from the very beginning to be of help in weight-loss maintenance.
As expected, a pharmacological treatment was rarely considered at the beginning of the weight-reducing program; it has limitations (44), but may be reconsidered in the weight-maintenance period after weight loss (45). Correctly, surgical approaches, which should be reserved for those with more serious clinical risks (45), were rarely considered in our medical units. In the group with Class III obesity, bariatric surgery was planned in 5.3% of cases (95% CI, 3.8-8.1). It will be of primary importance to analyze the specific indications given by different centers. Also in the area of treatment it is time to abandon concepts and preconcepts and move into evidence-based medicine.

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